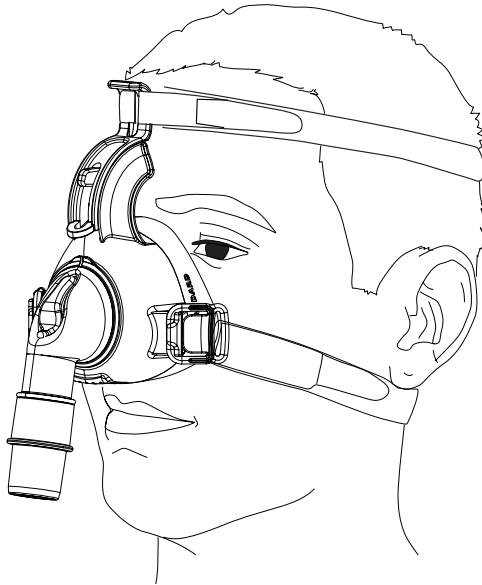


Assembly, Installation, and Operating Instructions

Invacare® Twilight™ II Nasal Mask



LATEX
FREE

USER: Before using this nasal mask, read this manual and save for future reference.

DEALER: This manual must be given to the end user.

For more information regarding
Invacare products, parts, and services,
please visit www.invacare.com



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SPECIAL NOTES

Signal words are used in this manual and apply to hazards or unsafe practices which could result in personal injury or property damage. Refer to the table below for definitions of the signal words.

SIGNAL WORD	MEANING
DANGER	Danger indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage.

NOTICE

THE INFORMATION CONTAINED IN THIS DOCUMENT IS SUBJECT TO CHANGE WITHOUT NOTICE.

Check ALL parts for shipping damage. If shipping damage is noted, DO NOT use. Contact Dealer/Carrier for further instruction.

The Invacare Model Twilight II Nasal Mask is intended to be used with positive airway pressure devices such as CPAP, for the treatment of adult obstructive sleep apnea. There is a port on the mask swivel to allow for pressure measurement. The mask is to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single or multiple patient reuse.

⚠ WARNING

DO NOT install, maintain or operate this equipment without first reading and understanding this manual. If you are unable to understand the **DANGERS/WARNINGS/CAUTIONS** and **INSTRUCTIONS**, contact your Home Healthcare provider before attempting to use this equipment - otherwise injury or damage may result.

Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. Accessories designed by other manufacturers have not been tested by Invacare and are not recommended for use with Invacare products.

GENERAL GUIDELINES

WARNING

GENERAL GUIDELINES contains important information for the safe operation and use of this product. **DO NOT** use this product or any available optional equipment without first completely reading and understanding these instructions and any additional instructional material such as **Owner's Manuals, Service Manuals or Instruction Sheets** supplied with this product or optional equipment. **If you are unable to understand the Warnings, Cautions or Instructions, contact a health care professional, dealer or technical personnel before attempting to use this equipment - otherwise, injury or damage may occur.**

This Twilight II Nasal Mask should be used only with CPAP systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP system is turned on and operating properly.

NEVER block the vent holes associated with the mask.

CPAP systems are intended to be used with special masks which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the mask exhalation vent holes. However, when the CPAP machine is not operating, not enough fresh air is provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

Using Headgear/Mask Assembly

NOTE: For this procedure, refer to FIGURE 1 on page 7 and FIGURE 2 on page 8.

NOTE: Wash the headgear before using it for the first time, as dye may run. Refer to Cleaning the Mask and Headgear on page 9.

NOTE: Invacare recommends washing your face before each use of the mask. This will remove excess facial oil and extend the life of the mask.

NOTE: Twilight II Nasal Mask is supplied fully assembled.

1. Remove the clear protective cover that is over the cushion.
2. Check for the following:
 - A. Ensure that the nasal cushion is fully attached.
 - B. Ensure the mask and hose swivels rotate properly.
 - C. Ensure the port plug is fully seated to seal the port, and the exhalation vent holes are clear.
3. Unfasten one or both of the headgear clips from the mask shell. Refer to FIGURE 2 on page 8.
4. Connect a standard 22 mm bore, 6-foot hose from your flow generator to the hose swivel by pressing the tube end over the hose swivel.
5. Turn on the flow generator.

⚠ WARNING

Flow generator MUST be on BEFORE placing the mask on your face.

6. Place the mask on your face with the headgear straps behind your head.
7. Fit the mask loosely over your nose and mouth.

NOTE: A minimal amount of pressure should be used to secure the nasal mask to the face.

8. Adjust the mask position on the nose by doing the following:
 - A. Press the forehead support adjustment tab.
 - B. Slide the forehead support up or down until it contacts the forehead and the upper portion of the cushion lightly touches the bridge of the nose.
 - C. Release the adjustment tab to lock it in the desired position.
9. Attach the headgear clips to the mask, and adjust the strap lengths as needed.

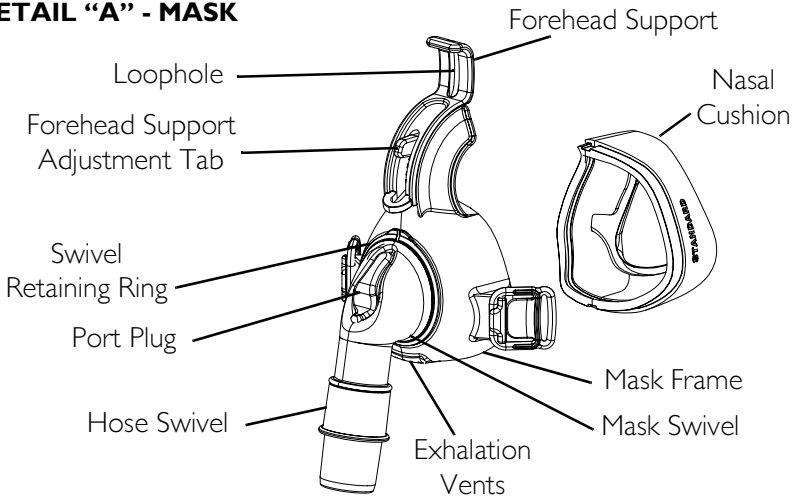
NOTE: Proper mask fit should allow full contact of the cushion without excessive pressure on the face.

NOTE: If a leak occurs, tighten or loosen the headgear straps by readjusting the hook-and-loop fastening strips.

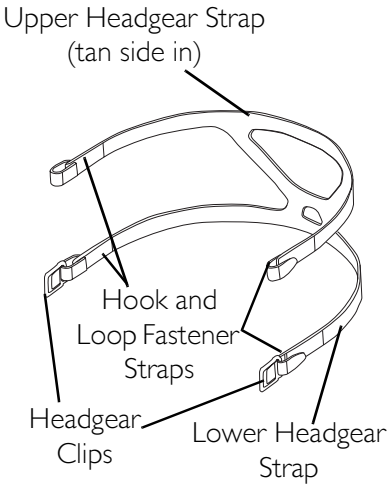
⚠ WARNING

DO NOT pull the straps too tight; this can cause skin irritation and may deform the nasal cushion, causing a leak. If the mask and headgear are adjusted correctly and a problem persists, contact your health care professional.

DETAIL "A" - MASK



DETAIL "B" - HEADGEAR



DETAIL "C" - FITTING

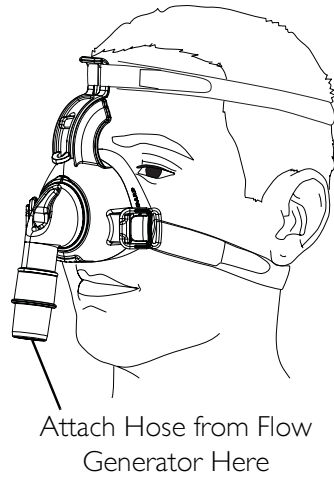


FIGURE I Using Headgear/Mask Assembly

Removing the Mask and Headgear

NOTE: For this procedure, refer to FIGURE 2.

1. Place your thumb and forefinger around one of the headgear clips.
2. Gently pull the headgear clip away from your face.

NOTE: It is not necessary to remove the headgear straps from the clips or the forehead support when removing the mask.

3. Pull the mask forward and lift it upwards and over the head.

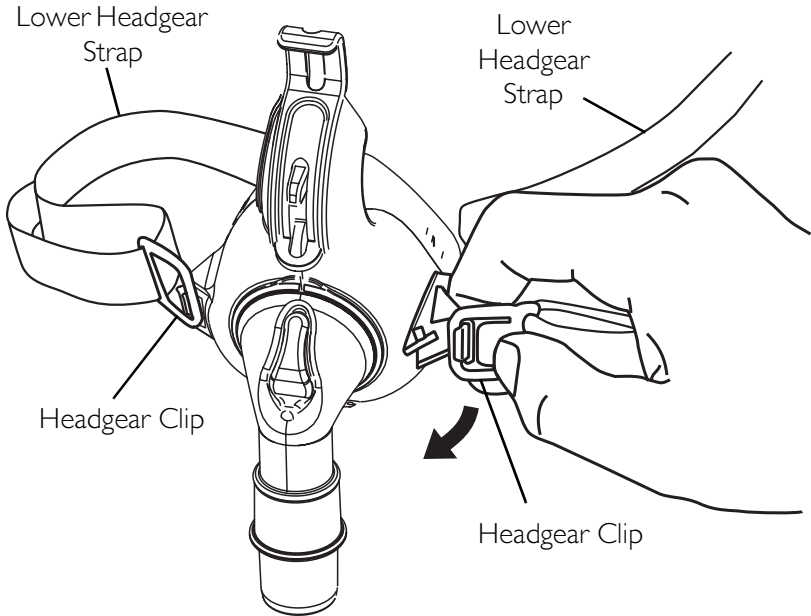


FIGURE 2 Removing the Mask and Headgear

Cleaning the Mask and Headgear

⚠ WARNING

DO NOT expose any part of the mask system to direct sunlight as it may cause mask deterioration.

After cleaning, **ALWAYS** rinse mask thoroughly. Insufficient rinsing of cleaning agents can result in severe skin rash, irritation and skin breakdown. Discontinue using the mask if there is an allergic reaction to any part of the mask and contact your health care professional.

For multi-patient use/reuse, clinicians should refer to the Mask Disinfection and Sterilization Guide (p/n 1130216).

The Twilight II Headgear cannot be disinfected or sterilized. Refer to instructions below for washing the headgear.

CAUTION

ALWAYS be sure to remove any foreign material (dirt, lint, etc.) from the exhalation vent holes.

DO NOT use bleach, chlorine, aromatic-based cleaning solutions, scented oils, or moisturizing or antibacterial soaps, to clean the nasal cushion, mask frame, headgear or air hose. These solutions may cause hardening and reduce the life of the product.

Alcohol may be used to clean the silicone nasal cushion **ONLY**. **DO NOT** use alcohol to clean the mask frame, headgear or air hose.

NOTE: Wash the mask system, except the headgear, after each use.

NOTE: Wash the headgear at least once per week.

NOTE: ALWAYS hand wash the headgear to increase the life of the product.

NOTE: It is not necessary to completely disassemble the mask for daily cleaning in the home. The mask can be cleaned and rinsed while still assembled. It is recommended, though, that the mask be disassembled for cleaning at least once per week of use.

1. Disassemble the mask. Refer to Disassembling the Mask for Cleaning on page 10.
2. Hand wash the headgear in warm or cool water using a mild detergent.
3. Rinse the headgear thoroughly and allow to air dry.
4. Hand wash the mask components using a mild detergent, such as dishwashing detergent, in warm water.
5. Rinse the mask components thoroughly and allow them to air dry.

⚠ WARNING

Washing the mask in a dishwasher is not recommended. Dishwasher cleaning and rinsing agents may leave a residue on the mask, which may cause skin irritation. DO NOT air dry in direct sunlight as it may cause mask deterioration.

Disassembling the Mask for Cleaning

NOTE: For this procedure, refer to FIGURE 1 on page 7 and FIGURE 3 on page 12.

1. Removing the mask. Refer to Removing the Mask and Headgear on page 8
2. Detach the six foot air hose from the hose swivel.
3. Detach the headgear from the forehead support by unfastening the hook-and-loop fastener tabs from the headgear and sliding the straps out of the slots in the forehead support (Detail “B” of FIGURE 1).

4. Remove the forehead support from the mask frame by pressing down the adjustment tab and sliding the support upward over the tab and off of the frame (Detail “A” of FIGURE 3).

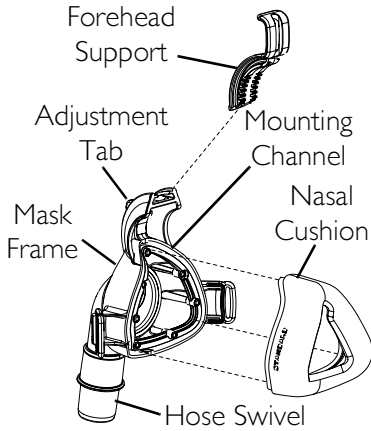
NOTE: It is not necessary to remove the forehead support after every use. It can be cleaned and rinsed while it is mounted to the mask shell.

5. Remove the nasal cushion from the mask frame by slowly pulling it out of the mounting channel.
6. Remove the swivel retaining ring on the outside of the mask swivel (Detail “B” of FIGURE 3).
7. Remove the mask swivel by rotating it through the opening in the mask frame.
8. Remove the hose swivel by pulling it off of the mask swivel.
9. Gently pull the port plug off the port on the mask swivel.
10. Remove the port plug from the mask swivel by holding it near the attachment point and gently pulling it straight out.

NOTE: Placing the components in the wash solution first can ease in the removal of the port plug from the mask swivel.

NOTE: It is not necessary to remove the plug completely from the mask swivel after every use. It can be cleaned and rinsed while it is attached to the mask frame.

DETAIL "A" - CUSHION AND FOREHEAD SUPPORT



DETAIL "B" - FRAME, RING, AND SWIVELS

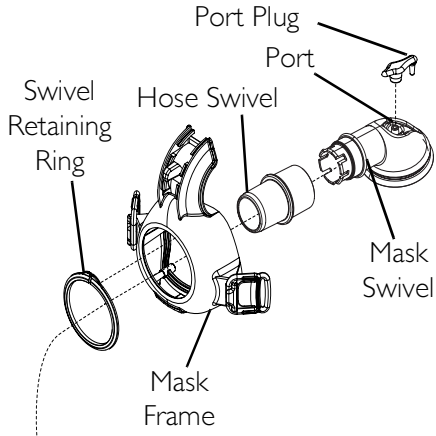


FIGURE 3 Cleaning the Mask and Headgear

Reassembling the Mask

⚠ WARNING

Replace the mask or mask component if damaged or deteriorated.

NOTE: For this procedure, refer to FIGURE 3 on page 12 and FIGURE 4 on page 15.

1. Replace the port plug onto the mask swivel by pushing the barb on the plug into the hole in the swivel while gently pulling the barb through from the other side, until the barb snaps into place (Detail "B" of FIGURE 3).
2. Push the port plug down over the port on the mask swivel to seal the port.
3. Snap the hose swivel onto the mask swivel.
4. Insert the mask swivel through the opening in the mask frame from the inside.

5. Lock the mask swivel into place on the outside of the mask frame by slipping the swivel retaining ring over the swivel.
6. Seat the swivel retaining ring into the groove on the swivel until it snaps in place.
7. Align the keying features at the top and bottom of the nasal cushion to the mating keying features in the mounting channel of the mask frame. The textured area above the keying feature at the top of the cushion aligns with the base of the adjustment tab. (Detail "B" of FIGURE 4).
8. Gently push the cushion ribbing down into the mounting channel on the mask frame.

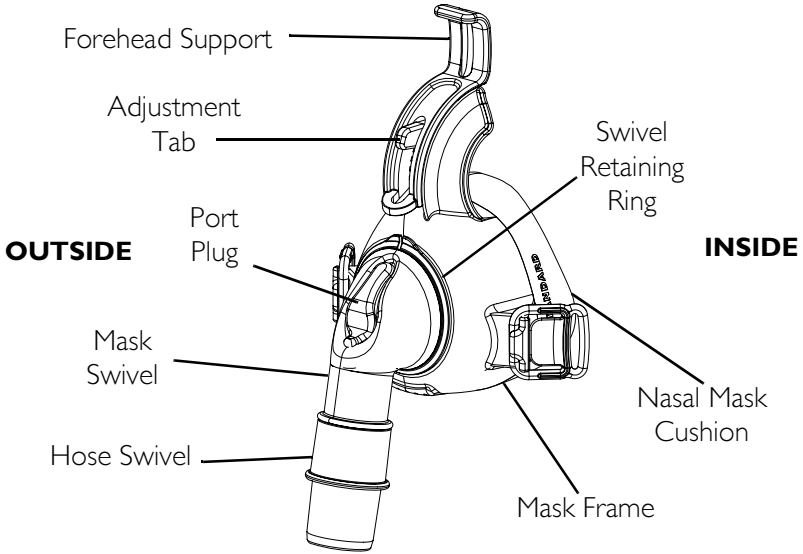
NOTE: The nasal cushion is completely seated in the mounting channel when the cushion and the mask frame meet forming a gapless seam around the outside edge.

9. If necessary, reattach the forehead support by doing the following (Detail "B" of FIGURE 4):
 - A. Align the channels on the outside of the support with the flanges on the mask frame.
 - B. Slide the forehead support into the top of the mask frame.
 - C. Press the forehead support adjustment tab.
 - D. Slide the end of the forehead support over the tab to the desired position.
 - E. Release the adjustment tab to lock it in the desired position.
10. Attach the headgear to the mask by sliding the upper headgear strap through the loophole of the forehead support. The tan side of the headgear goes against the head and the Invacare label will be on the outside of the upper strap.

REASSEMBLING THE MASK

11. Loosely secure each side of the upper headgear strap by folding it back and, using the hook-and-loop fastening strips, secure the excess straps to the upper headgear strap.
12. Slide the lower headgear strap through the loopholes of the headgear clips.
13. Loosely secure each side of the lower headgear strap by folding it back and, using the hook-and-loop fastening strips, secure the excess straps to the lower headgear strap.

DETAIL "A" - FRONT



DETAIL "B" - REAR

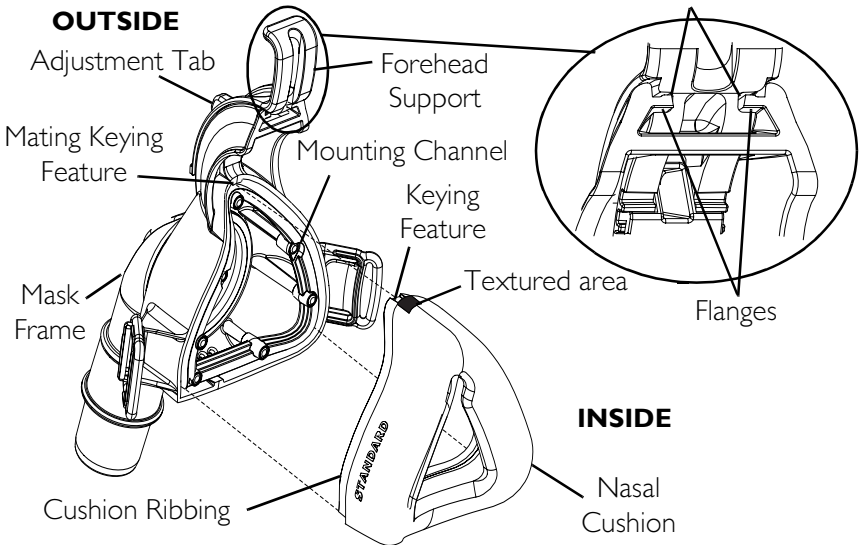


FIGURE 4 Cleaning the Mask and Headgear

Storage and Operating Conditions

OPERATING TEMPERATURE:	50 to 104°F (10 to 40°C)
STORAGE TEMPERATURE:	- 4 to 158°F (-20 to 70°C)

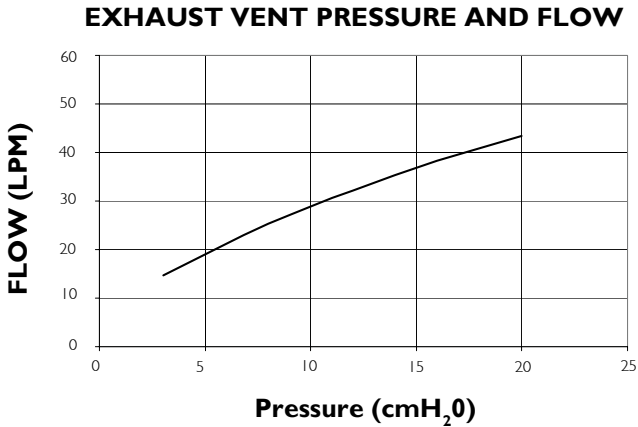
MASK DEADSPACE VOLUME (ml)		
Small	Standard	Large
85	102	108

Typical values for Pressure Drop

0.12 cmH₂O (.012 kPa) at flow of 50 LPM

0.41 cmH₂O (.040 kPa) at flow of 100 LPM

Pressure and Flow Characteristic



Replacement Items/Accessories

The following Invacare Twilight II Mask replacement items and accessories are available:

- Small Nasal Cushion - ISP2110SM
- Standard Nasal Cushion - ISP2110STD
- Large Nasal Cushion - ISP2110L
- Headgear - 1122733
- Chin Support - 1122734

NOTES

WARRANTY

PLEASE NOTE: THE WARRANTY BELOW HAS BEEN DRAFTED TO COMPLY WITH FEDERAL LAW APPLICABLE TO PRODUCTS MANUFACTURED AFTER JULY 4, 1975.

This warranty is extended only to the original purchaser/user of our products.

This warranty gives you specific legal rights and you may also have other legal rights which vary from state to state.

Invacare warrants the Twilight II Mask to be free from defects in materials and workmanship for a period of 90 days from date of purchase. If within such warranty period any such product shall be proven to be defective, such product shall be repaired or replaced, at Invacare's option. This warranty does not include any labor or shipping charges incurred in replacement part installation or repair of any such product. Invacare's sole obligation and your exclusive remedy under this warranty shall be limited to such repair and/or replacement.

For warranty service, please contact the dealer from whom you purchased your Invacare product. In the event you do not receive satisfactory warranty service, please write directly to Invacare at the address on the back cover, provide dealer's name, address, date of purchase, indicate nature of the defect and, if the product is serialized, indicate the serial number. Do not return products to our factory without our prior consent.

LIMITATIONS AND EXCLUSIONS: THE FOREGOING WARRANTY SHALL NOT APPLY TO SERIAL NUMBERED PRODUCTS IF THE SERIAL NUMBER HAS BEEN REMOVED OR DEFACED, PRODUCTS SUBJECTED TO NEGLIGENCE, ACCIDENT, IMPROPER OPERATION, MAINTENANCE OR STORAGE, COMMERCIAL OR INSTITUTIONAL USE, PRODUCTS MODIFIED WITHOUT INVACARE'S EXPRESS WRITTEN CONSENT (INCLUDING, BUT NOT LIMITED TO, MODIFICATION THROUGH THE USE OF UNAUTHORIZED PARTS OR ATTACHMENTS; PRODUCTS DAMAGED BY REASON OF REPAIRS MADE TO ANY COMPONENT WITHOUT THE SPECIFIC CONSENT OF INVACARE, OR TO A PRODUCT DAMAGED BY CIRCUMSTANCES BEYOND INVACARE'S CONTROL, AND SUCH EVALUATION WILL BE SOLELY DETERMINED BY INVACARE. THE WARRANTY SHALL NOT APPLY TO PROBLEMS ARISING FROM NORMAL WEAR OR FAILURE TO ADHERE TO THE FOLLOWING INSTRUCTIONS.

THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND THE SOLE REMEDY FOR VIOLATIONS OF ANY WARRANTY WHATSOEVER, SHALL BE LIMITED TO REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT PURSUANT TO THE TERMS CONTAINED HEREIN. THE APPLICATION OF ANY IMPLIED WARRANTY WHATSOEVER SHALL NOT EXTEND BEYOND THE DURATION OF THE EXPRESS WARRANTY PROVIDED HEREIN. THE MANUFACTURER SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES WHATSOEVER.

THIS WARRANTY SHALL BE EXTENDED TO COMPLY WITH STATE/PROVINCIAL LAWS AND REQUIREMENTS.



Yes, you can.

Invacare Corporation

USA
One Invacare Way
Elyria, Ohio USA
44036-2125
800-333-6900

Tech Services
800-832-4707

www.invacare.com

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